

Certificate of Analysis

Productname: Ichthammolum

Inspection No: I05697/0821/536
Batchnumber: 21C25-T16-089704
Expiration date: 31.10.2026
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 30.11.2020

Sample Unit: 0 x 50 g
Batch Size: 185 x 50 g

Identification of producer: V01339
Batch no. of vendor: 007112041509/20

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Dense, blackish-brown liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	Conform	Conform		Precipitate	Fagron CZ
Identification B	Conform	Conform		Ammonium salts	Fagron CZ
Identification C	Conform	Conform		Sulfate	Fagron CZ
TESTS					
Acidity or alkalinity	Conform	Conform			Fagron CZ
Relative density	1,040 - 1,085	1,054		50% V/V	Fagron CZ
Sulfated ash	≤0,3	0,1	%		Fagron CZ
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer
ASSAY					
dry matter	50,0 - 56,0	50,0	%	105°C	Fagron CZ
total ammonia	4,5 - 7,0	5,5	%	Dried	Fagron CZ
organically combined sulfur	≥10,5	15,3	%	Dried	Fagron CZ
sulfur in the form of sulfate	≤20,0	16,1	%		Fagron CZ

Performed by: Ing. Petra Drábková

Responsible: Ing. Pavel Mišák, QC
 PharmDr. Ivana Urbánková, QA

Date: 22.07.2021

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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